K002238

AUG 22 2000

CAPIOX® CX*AF200X Arterial Filter
510(k) Summary and Certification

Submitter Information:

Name and Address:
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton MD 21921

Contact Person:
Garry A. Courtney
Regulatory Affairs Specialist
Telephone: 1-800-283-7866, Ext. 7420

Date of Preparation: June 26, 2000

Device Names:

Proprietary Name: CAPIOX® SX Hardshell Reservoir with X-Coating
Common Name: Blood Reservoir
Classification Name: Cardiopulmonary Bypass Blood Reservoir

Predicate Device:

Terumo Cardiovascular Systems Corporation has identified the CAPIOX® SX Hardshell Reservoir as the predicate device for the determination of substantial equivalence. The CAPIOX® SX Hardshell Reservoir device was cleared with Premarket Notification K982223 on September 10, 1998.

Intended Use:

The CAPIOX® SX Hardshell Reservoir with X-Coating is a hardshell reservoir used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal. The device is intended for use in procedures lasting up to 6 hours in duration.

The CAPIOX® SX Hardshell Reservoir with X-Coating is also used for post-operative chest drainage and autotransfusion procedures to aseptically return the blood to the patient for blood volume replacement.

The CAPIOX® SX Hardshell Reservoir with X-Coating is also used with the vacuum-assisted venous return technique during cardiopulmonary bypass.

The intended use is exactly the same for the CAPIOX® SX Hardshell Reservoir with X-Coating and the predicate CAPIOX® SX Hardshell Reservoir (K982223).

Principles of Operation and Technology:
The CAPIOX® SX Hardshell Reservoir with X-Coating utilizes gravity and/or external vacuum for blood collection into the reservoir. Vacuum can be applied to the reservoir to increase venous return.

Air removal in the CAPIOX® SX Hardshell Reservoir with X-Coating is facilitated by defoamers (located within the reservoir) and the tendency of air to rise through liquid.

Particulate removal in the CAPIOX® SX Hardshell Reservoir with X-Coating is facilitated by the blood flow pathway through filters contained within the reservoir.

The principles of operation and technology are exactly the same for the CAPIOX® SX Hardshell Reservoir with X-Coating and the CAPIOX® SX Hardshell Reservoir (K982223).

Design and Materials:
The design and materials that are used in the construction of the CAPIOX® SX Hardshell Reservoir with X-Coating are exactly the same design and materials that are used in the CAPIOX® SX Hardshell Reservoir - with the exception of the X-Coating polymer. Use of the X-Coating polymer has been demonstrated to be safe and effective in other legally marketed devices (K993772), and raises no new issues of safety or effectiveness when applied to the CAPIOX® SX Hardshell Reservoir.

Specifications:
The following specifications are applicable to the X-Coated and non-coated CAPIOX® SX Hardshell Reservoirs:

Specifications	CAPIOX® SX Hardshell Reservoir with X-Coating	CAPIOX® SX Hardshell Reservoir – (Non-Coated)
Minimum Operating Volume	200 mL	200 mL
Blood Storage Capacity	4000 mL	4000 mL
Blood Flow Rate(s)	Venous Flow: Min: 0.5 L/Min. Max: 7.0 L/Min. Cardiotomy Flow: Min: 0.5 L/Min. Max: 5.0 L/Min. Combined Flow: Max: 7.0 L/Min.	Venous Flow: Min: 0.5 L/Min. Max: 7.0 L/Min. Cardiotomy Flow: Min: 0.5 L/Min. Max: 5.0 L/Min. Combined Flow: Max: 7.0 L/Min.
Cardiotomy Filtration Efficiency	Greater than 90% efficiency for particles ≥ 20μ	Greater than 90% efficiency for particles ≥ 20μ

The specifications are exactly the same for the CAPIOX® SX Hardshell Reservoir with X-Coating and the CAPIOX® SX Hardshell Reservoir, K982223.

Performance:
The following verification tests were performed to demonstrate that substantial equivalence of the CAPIOX® SX Hardshell Reservoir with X-Coating to the CAPIOX® SX Hardshell Reservoir (K982223).

- Cardiotomy Section – Defoaming Test
- Cardiotomy Section – Pressure Drop Test
- Cardiotomy Section – Filtration Efficiency Test
- Cardiotomy Section – Effects on Cellular Blood Components Test
- Venous Section – Defoaming Test
- Venous Section – Pressure Drop Test
- Venous Section – Flow Rate Test
- Venous Section – Effects on Cellular Blood Components Test
- Biocompatibility Tests

The results from the above testing demonstrated that there are no clinically significant performance-related differences between the modified device and the unmodified device. Furthermore, no new issues of safety and effectiveness are recognized as a result of the modification.

Substantial Equivalence:
Therefore, the performance of the CAPIOX® SX Hardshell Reservoir with X-Coating is substantially equivalent to the performance of the CAPIOX® SX Hardshell Reservoir (K982223).

Additional Safety Information:
- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.

- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Terumo Cardiovascular Systems Corporation conducted the biocompatibility studies recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

- Terumo Cardiovascular Systems Corporation also conducted studies for materials characterization, including physico-chemical profiles and FT-IR scans. No adverse conditions were noted.

- The X-Coating polymer that is applied to the blood-contacting surfaces of the device was also evaluated in an *in-vivo* animal study using swine as the test subjects. No adverse conditions were noted.

- *In Vitro* studies using human blood were conducted to demonstrate the hemocompatiblity of the polymer coating.

- Safety evaluations of the polymer coating were conducted by Terumo Corporation (Japan). No adverse conditions were noted. Those studies include:

    - Acute Systemic Toxicity Testing (in Rats)
    - Genotoxicity Testing – Bacterial Reverse Mutation
    - Genotoxicity Testing – Chromosome Aberration
    - Sensitization (in Guinea Pigs)

The additional safety evaluations determined that use of the X-Coating polymer does not create any adverse conditions or new safety issues.

Conclusion:
In summary, the CAPIOX® SX Hardshell Reservoir with X-Coating is substantially equivalent in intended use, principles of operation and technology, design and materials, specifications, and performance to the unmodified CAPIOX® SX Hardshell Reservoir (K982223). The use of the X-Coating polymer raises no new issues of safety and/or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2000

Terumo Medical Corporation
C/O Garry A. Courtney
Regulatory Affairs
125 Blue Ball Road
Elkton, MD 21921

Re: K002238
Trade Name: CAPIOX® SX Hardshell Reservoir with X-Coating
Regulatory Class: II (two)
Product Code: DTN
Dated: August 3, 2000
Received: August 4, 2000

Dear Mr. Courtney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002238

Device Name: **CAPIOX SX Hardshell Reservoir with X-Coating**

Indications For Use:

The CAPIOX® SX Hardshell Reservoir with X-Coating is a hardshell reservoir used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line. The reservoir contains filters to remove particulate matter and defoamers to facilitate air bubble removal. The device is intended for use in procedures lasting up to 6 hours in duration.

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The CAPIOX® SX Hardshell Reservoir with X-Coating is also used with the vacuum-assisted venous return technique during cardiopulmonary bypass.

The CAPIOX® SX Hardshell Reservoir with X-Coating is intended to reduce platelet adhesion on the surfaces of the device.

Garry A. Courtney
Regulatory Affairs Associate
Terumo Cardiovascular Systems Corp

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K002238